

Betesil®

2.250 mg medicated plaster
Betamethasone valerate



Inflammatory
skin conditions

Potent,
Practical
medicated
plaster

with a uniform
metered dose
delivered directly to
the affected area

A medicated plaster containing a potent steroid that **treats, protects,** and provides a **metered dose** for inflammatory skin conditions and plaque psoriasis.⁽¹⁾

BETESIL® is indicated in adults for the treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Also suitable for chronic plaque psoriasis localized in difficult to treat areas (e.g. knees, elbows and anterior face of the tibia on an area not greater than 5% of the body surface). For further details please see the Betesil® 2.250 mg medicated plaster Summary of Product Characteristics (SmPC)⁽¹⁾.

Another innovative product from
dermauk.co.uk



Diagnosis

BETESIL[®] is indicated in adults for inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as

- eczema
- lichenification
- lichen planus
- granuloma annulare
- palmoplantar pustulosis
- mycosis fungoides.⁽¹⁾

Also, treatment of chronic plaque psoriasis in difficult-to-treat areas (such as knees, elbows and shins) on a maximum of 5% of the total body surface area.

BETESIL[®] in a medicated plaster form provides Betamethasone valerate under occlusion and an alternative method of administration.

Once a significant improvement has been achieved, it may be replaced by another form of less potent corticosteroid.

Elbows



Knees

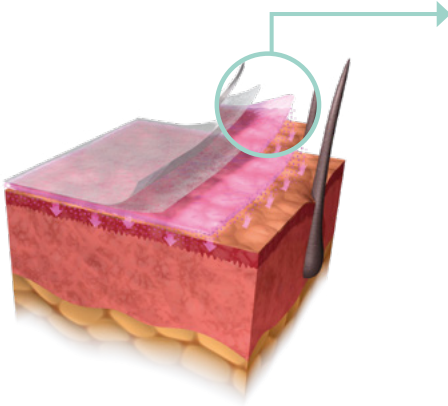


Shins OR anterior face of the tibia



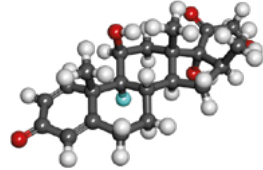
Uniform metered dose

A uniform metered dose of Betamethasone valerate



For action targeted on the lesion

- The medicated plaster contains 2.250 mg of Betamethasone valerate



- Action is targeted specifically on the application area



- 1 plaster lasts 24 hours*



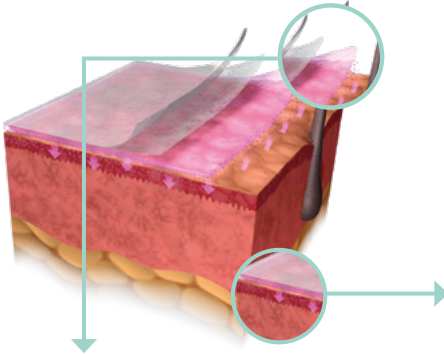
*Max daily dose 6 plasters,
Max treatment period 30 days

Betesil[®]

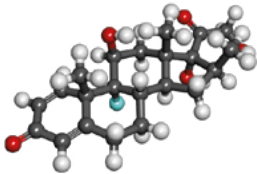
2.250 mg medicated plaster
Betamethasone valerate

Treatment

Mechanism of Action



Betamethasone valerate



Localised, uniform concentration of Betamethasone valerate⁽¹⁾

Potent Action

- Anti-inflammatory
- Anti-itch⁽⁵⁾
- Vasoconstrictive⁽⁵⁾

Betamethasone valerate is held back by the stratum corneum⁽¹⁾

Only small amounts reach the dermis where it can be absorbed⁽¹⁾

Advantages of BETESIL[®] Medicated Plaster

- Helps deliver a more accurate dose of steroid due to its pharmaceutical form
- Protection of the lesion via a medicated plaster
- Superior efficacy versus Betamethasone cream^(2, 3)
- Occlusive nature of dressing assists skin rehydration and healing
- Gentle adhesion to support minimal cell-stripping
- Efficacy equivalent to Calcipotriol-Betamethasone dipropionate (50 µg - 0.5mg/g) ointment⁽⁴⁾
- One month's use after opening each plaster sachet.⁽¹⁾
Keep cutting down for multiple treatments per plaster
- Aluminium storage pouches ensure product integrity once open/cut⁽¹⁾
- Supplied with adhesive strips to secure the dressing if required



Protecting the Lesion

A protective plaster

Protecting the lesion

Suitable for hard-to-treat areas

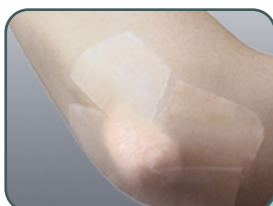
- Knees
- Elbows
- Shins

Cut to fit the size of the lesion.
Apply the adhesive side of the medicated plaster to the affected area and remove the protective film



Medicated plaster

- Discreet
- Flexible, can be cut to size to fit the area to be treated*
- Easy application
- Does not stain clothes or bedding
- Acts as a barrier, reducing the risk of further damage to the lesion from trauma or scratching⁽²⁾



*Visit betesil.co.uk/HCP for a selection of downloadable cutting templates and to watch our application video

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Case Study

A BETESIL[®] Medicated Plaster Case Study

With Polly Buchanan, Community Nurse Dermatology Specialist

- Patient presents with long-term eczematous psoriasis.
- Previous mild-moderate steroids did not resolve the condition.
- Patient was prescribed BETESIL[®] once daily for four weeks.
- After one month of treatment using BETESIL[®], the resistant plaques had completely resolved.



Eczematous Psoriasis Before Treatment



After One Month of Treatment using BETESIL[®]



Scan to read
full case study

Betesil[®]
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Clinical Studies

NALDI Study in plaque psoriasis⁽²⁾: BETESIL[®] more efficacious than Betamethasone Cream 0.1%

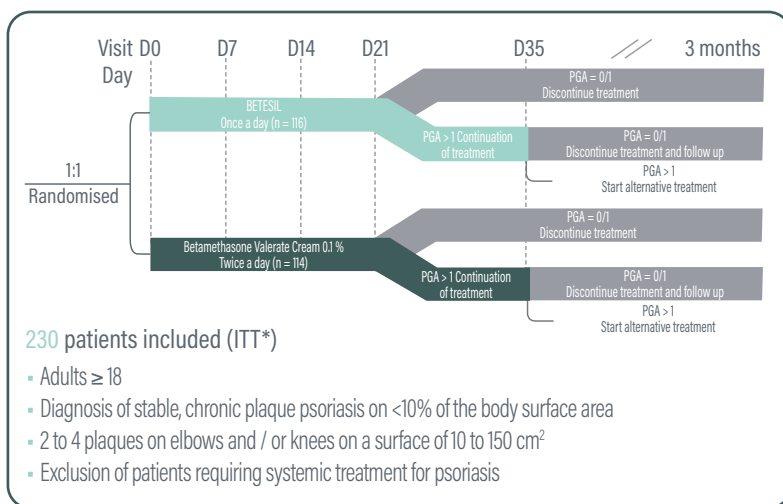
A Prospective and controlled study

International, multi-centre, prospective, randomised, assessor-blind, parallel group, active-controlled phase III study comparing BMV plaster 0.1% versus Betamethasone valerate 0.1% cream.

Objective

To evaluate the efficacy and safety of BETESIL[®] and Betamethasone valerate cream 0.1% in patients with mild-to-moderate chronic plaque psoriasis.

Study Diagram



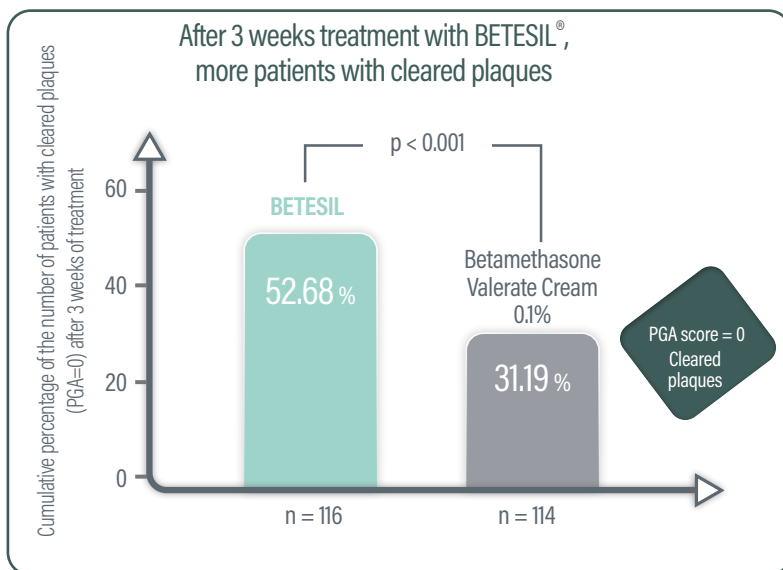
Outcome measures

Number of patients with cleared plaques (PGA score ** = 0) after 3 weeks of treatment (ITT*)

BETESIL[®] like other potent steroids, is a first-line treatment in plaque psoriasis excluding sensitive areas (face and skin folds).

Once a significant improvement has been achieved, it may be replaced by another form of less potent corticosteroid.

Clinical Studies



Equivalent safety

- Safety is equivalent for both treatment groups, with 14 patients presenting with adverse effects in each group. The most common side effects are infections and infestations (6 in the BETESIL[®] group and 7 in the Betamethasone valerate cream 1% group).
- No serious adverse effects have been identified in the BETESIL[®] group.

Known common adverse events ($\geq 1/100$; $\leq 1/10$)

- Skin atrophy
- Boils
- Telangiectasia
- Erythema
- Pustules
- Pruritus
- Papules
- Skin erosion

* ITT: Intent to Treat population

** PGA: Psoriasis Global Assessment measuring the status of psoriasis where 0 = absent and 5 = severe, scored here between D0 and D21 by blind evaluators based on photographs.

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Clinical Studies

Ortonne Study in plaque psoriasis: BETESIL[®] is non-inferior versus a combination of Betamethasone 0.5 mg - Calcipotriol 50µg/g Ointment⁽⁴⁾

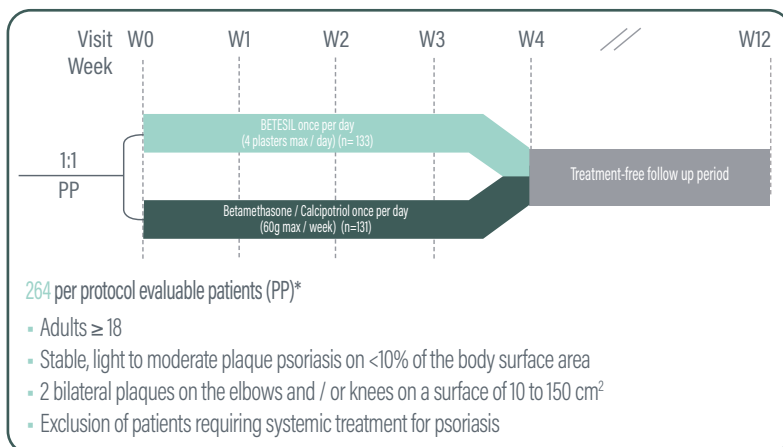
A Prospective and controlled study

Multi-centre, prospective, randomised, investigator-blinded, controlled, non-inferiority trial versus Betamethasone Dipropionate/Calcipotriol combination.

Objective

The objective of this study was to compare short-term efficacy and safety of the BMV dressing to a fixed combination 50 mcg–0.5 mg/g calcipotriol–betamethasone dipropionate ointment in patients with mild to moderate chronic plaque psoriasis (CPP) over a 4-week treatment period.

Study Diagram



Outcome measures

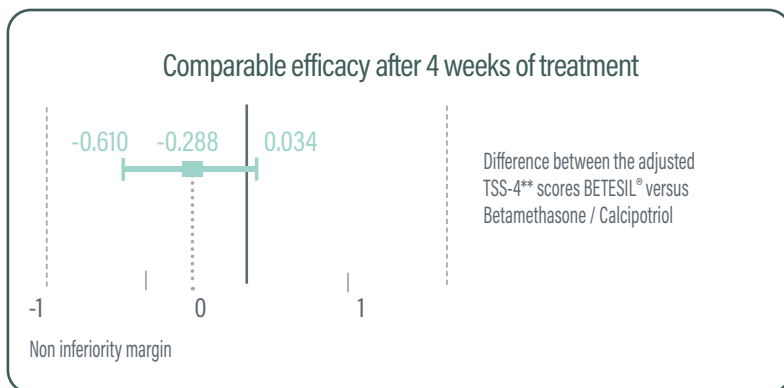
Evaluation of efficacy at 4 weeks of treatment with TSS-4 Global score ** (PP*).

Non-inferiority hypothesis: For BETESIL[®] to be considered not inferior, the lower limit of the 95% confidence interval for the difference between the two treatments must be greater than -1.

BETESIL[®] like other potent steroids, is a first-line treatment in plaque psoriasis excluding sensitive areas (face and skin folds).

Once a significant improvement has been achieved, it should be replaced by another form of steroid and the frequency should be gradually reduced.

Clinical Studies



- Non-significant difference
- CI*** 95% >-1 (non-inferiority margin)

BETESIL[®] is non inferior to the combination of Betamethasone 0.5 mg - Calcipotriol 50 µg/ g

Equivalent safety

- Safety is equivalent for both treatment groups, with the proportion of patients with adverse effects in the BETESIL[®] group being 8.48% (165 patients, ITT population), and in the combination of Betamethasone / Calcipotriol group being 9.43% (159 patients, ITT population)
- The most common adverse effect was nasopharyngitis (2 patients in the BETESIL[®] group and 4 in the Betamethasone/Calcipotriol group)
- Only 1 side effect is related to treatment (burning sensation) in the BETESIL[®] group

* PP: Per protocol.

** TSS-4: 4-item Total Severity Score: redness/erythema, scale/crusting, thickening/elevation of plaques, pruritus.

*** CI - Confidence Interval

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Abbreviated Prescribing Information for BETESIL® 2.250 mg medicated plaster

Abbreviated Prescribing Information for BETESIL® 2.250 mg medicated plaster. Please refer to the full Summary of Product Characteristics (SmPC) prior to prescribing.

Presentation: A colourless, medicated plaster, containing 2.250 mg of betamethasone valerate (corresponding to 1.845 mg of betamethasone).

Indications: Indicated in adults for the treatment of inflammatory skin disorders which do not respond to treatment with less potent corticosteroids, such as eczema, lichenification, lichen planus, granuloma annulare, palmoplantar pustulosis and mycosis fungoides. Also suitable for chronic plaque psoriasis localized in difficult to treat areas (e.g., knees, elbows, and anterior face of the tibia). Overall, the surface area treated with BETESIL should not exceed 5% of the body surface).

Dosage and Administration: Apply the medicated plaster to the skin area to be treated once a day. Do not exceed the maximum daily dose of six medicated plasters and the maximum treatment period of 30 days. A new medicated plaster must be applied every 24 hours. Wait at least 30 minutes between one application and the next.

Once an appreciable improvement has been obtained, discontinue application and consider continuing treatment with a less potent corticosteroid. The safety and efficacy in children aged <18 years has not yet been established. For full details of usage please refer to the relevant section of the SmPC. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Cutaneous tuberculosis and viral skin infections (including vaccinia pustules, herpes zoster and herpes simplex). Exudative lesions and primary skin infections caused by fungi or bacteria (e.g. syphilitic skin lesions). Acne, acne rosacea, perioral dermatitis, skin ulcers, burns and frostbite. Do not apply to face. Do not use on patients under 18 years of age. **Precautions and Warnings:** Caution in patients with visual disturbance. Cataract, glaucoma or rare diseases such as central serous chorioretinopathy have been reported with systemic and topical corticosteroid use. Use of topical corticosteroids on large areas of the body and for prolonged periods, as well as the use of an occlusive dressing can cause a temporary suppression of the hypothalamus-pituitary-adrenal axis, leading to secondary hypoadrenalism and adrenal hypercorticism, including the Cushing's syndrome. In these situations, treatment should be discontinued gradually and under strict control of a doctor due to the risk of acute adrenal insufficiency. Sudden withdrawal of the treatment in psoriatic patients, may also lead to symptoms exacerbation or generalized pustular psoriasis. Prolonged use in diffuse psoriasis (except for the treatment of isolated plaques) or diffuse eczema or application on lesions located in skin folds is not recommended, as these conditions may increase systemic absorption. The use of occlusive bandages, especially with plastic material, may increase this effect. The symptoms of this are: facial redness, weight changes (fat increase in body and face and loss in legs and arms), reddish streaks on stomach, headache, menstrual alterations, or an increase in unwanted face and body hair. In this regard, it is known that certain skin areas (face, eyelids, armpits, scalp and scrotum) absorb more easily than others (skin on the knees, elbows, palms of the hands and feet on

soles). Long term continuous or inappropriate use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). Application of topical medicinal products, especially if prolonged, may give rise to hypersensitivity reaction. Skin atrophy has also been reported after three-week treatment periods. In case of drug intolerance, for example if skin irritation or contact dermatitis occurs during treatment, it is necessary to stop the medicated plaster application and start suitable treatment (see section 4.8 of the SmPC, "Undesirable effects"). Corticosteroids may affect the results of the nitroblue tetrazolium test (NBT) for diagnosing bacterial infections by producing false negatives. Medicinal products containing corticosteroids must be used with caution in patients with impaired immune system function (T-lymphocytes) or in those being treated with immunosuppressive therapy. The product contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause hypersensitivity reactions (possibly delayed). There are no or limited amount of data from the use of betamethasone valerate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). Betesil is not recommended during pregnancy and in women of childbearing potential not using contraception. **Undesirable Effects:** Commonly reported side effects are skin and subcutaneous tissue disorders, occurring in about 15% of patients treated. All cases reported during controlled clinical trials were found to be common ($\geq 1/100$, $< 1/10$): skin atrophy, telangiectasia, pustules, papules, furuncle, erythema, pruritus, skin erosion. These undesirable effects are local effects on the skin in the plaster application area. The frequency of withdrawal syndrome is not known. No systemic effects have been observed. Prescribers should consult the summary of product characteristics for other more general considerations on side effects reported with use of corticosteroids for cutaneous use. **Precautions for Storage:** Do not store above 25°C. Store the medicated plaster in its original sachet to preserve its integrity. For storage conditions after first opening of the medicinal product, see SmPC. **Legal Category:** POM. **Package Quantities:** A carton containing four or eight envelopes, each envelope contains one 75 cm x 10 cm medicated plaster containing 2.250 mg of betamethasone valerate. **Marketing Authorisation Number and Holder:** PL 21039/0009. IBSA FARMACEUTICI ITALIA S.R.L. VIA MARTIRI DI CEFALONIA 2 LODI -26900 ITALY. **Basic NHS Price:** £13.98 per pack of four BETESIL® 2.250 mg medicated plasters. £2746 per pack for eight BETESIL® 2.250 mg medicated plasters. **Date of preparation of Prescribing Information:** November 2023. **Further information** can be found in the Summary of Product Characteristics or from: Derma UK Ltd, The Toffee Factory, Lower Steenberg's Yard, Quayside, Ouseburn, Walker Rd, Newcastle upon Tyne, Tyne and Wear, NE1 2DF.

Adverse events should be reported.
Information about adverse event reporting can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to
Derma UK Ltd, UK on 0191 375 9020.

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A medicated plaster containing a potent steroid that **treats, protects,** and provides a **metered dose** for inflammatory skin conditions and plaque psoriasis.⁽¹⁾



How Often?

1 plaster per plaque every 24 hours

How Many?

6 plasters/day maximum

Secure?

Adhesive strips included for securing dressings if required

What's in the pack?

Box of 4 or 8 medicated plasters (10 x 7.5 cm)

Maximum Treatment?

30 days until plaque improves, then if needed continue treatment with a less potent corticosteroid

(1) Derma UK Ltd, 'Summary of Betesil® Product Characteristics (SmPC)', 2022.

(2) Naldi L et al, 'Efficacy and Safety of the Betamethasone Valerate 0.1% Plaster in Mild-to-Moderate Chronic Plaque Psoriasis: A Randomized, Parallel-Group, Active-Controlled, Phase III Study'. American Journal of Clinical Dermatology, vol. 12, no 3, 2011, pp. 191-2011.

(3) Pacifico A et al, 'A new formulation of an occlusive dressing containing betamethasone valerate 0.1% in the treatment of mild to moderate psoriasis'. Journal of European Academy of Dermatology and Venereology, no 20, 2006, pp. 153-157.

(4) Ortonne JP, et al, 'Betamethasone valerate dressing is non-inferior to calcipotriol-betamethasone dipropionate ointment in the treatment of patients with mild-to-moderate chronic plaque psoriasis: results of a randomized assessor-blinded multicentre trial'. Journal of European Academy of Dermatology and Venereology, vol. 28, no 9, 2014, pp. 1226-34.

(5) Amici JM, Ly S, 'Role of betamethasone valerate 2.250 mg medicated plaster in the treatment of psoriasis and other dermatological pathologies: a review' Drugs in Context, 2018. <https://www.drugsincontext.com/wp-content/uploads/2018/08/dic.212539.pdf> (Last accessed 29th August 2025).